

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

MAUREEN TOOMEY

Plaintiff,

V.

Case No. 07 CV 7173

SANOFLI-AVENTIS U.S. INC. F/K/A/  
AVENTIS PHARMACEUTICALS INC.,  
F/K/A HOECHST MARION ROUSSEL,  
INC.; WALGREEN CO.; and BOND DRUG  
COMPANY OF ILLINOIS D/B/A/  
WALGREEN CO., a corporation,

Judge Blanche M. Manning  
Magistrate Judge Martin C. Ashman

Defendant.

**ANSWER, JURY DEMAND AND SEPARATE AND AFFIRMATIVE DEFENSES**

COME NOW sanofi-aventis U.S. Inc. (improperly named in this action, and erroneously referred to in the style of the Complaint as “sanofi-aventis U.S. Inc. F/K/A Aventis Pharmaceuticals Inc., F/K/A Hoechst Marion Roussel, Inc.”) and Aventis Pharmaceuticals Inc. (not properly named as a party herein, and hereinafter referred to as “API”) (hereinafter collectively referred to as the “Defendants”) and file their Answer, Jury Demand and Separate and Affirmative Defenses (“Answer”) to Plaintiff’s Complaint as follows:

## PRELIMINARY STATEMENT

1. All responses provided hereafter are made in a good faith attempt to respond to Plaintiff's Complaint within the time limits prescribed by law. As further information is disclosed clarifying Plaintiff's claims and allegations pertinent to those claims, Defendants will provide, by way of amendment to this Answer as necessary or by response to proper discovery, information correcting or clarifying any responses made hereafter which are later learned to have

been provided in error.

2. Defendant sanofi-aventis U.S. Inc. is an improper party to this action and should be dismissed. Defendant sanofi-aventis U.S. Inc. denies that it is formerly known as “Aventis Pharmaceuticals Inc.” or “Hoechst Marion Roussel, Inc.” Rather, Defendants state that API is a separate and distinct entity that currently exists for potential liability arising out of Ketek® use prior to January 1, 2006. Defendants further state that Hoechst Marion Roussel, Inc. no longer exists, having transferred its business to API.

3. Defendants state that API is not named as a party to this action. Accordingly, no answer is required on behalf of API. To the extent an answer is required, and in an abundance of caution, API answers the allegations contained in Plaintiff’s Complaint directed to it, and reserves any and all affirmative defenses, including without limitation, misjoinder of API in its correct, independent capacity, lack of personal jurisdiction and improper service of process.

4. Defendants incorporate this Preliminary Statement into their responses to each and every Paragraph of Plaintiff’s Complaint hereafter.

### **RESPONSE TO PLAINTIFF’S ALLEGATIONS**

Responding to the specifically enumerated Paragraphs of Plaintiff’s Complaint, Defendants state as follows:

1. That prior to August 24, 2005, SANOFI-AVENTIS was a manufacturer of many prescription drugs including, but not limited to, the drug commonly referred to as Ketek.

**ANSWER:** API admits only that, at times, it manufactured Ketek®. Sanofi-aventis U.S. Inc. denies that it manufactured Ketek® and denies all allegations contained in Paragraph 1 of Plaintiff’s Complaint directed to it. Except as stated herein, Paragraph 1 of Plaintiff’s Complaint is denied.

2. That prior to August 24, 2005, WALGREENS was a distributor of many prescription drugs including, but not limited to, the drug commonly referred to as Ketek.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

3. That on or about August 24, 2005, KIMBERLY RICUARTE was a licensed physician in the State of Illinois and all of its branches.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

4. That on or about August 24, 2005, KIMBERLY RICUARTE prescribed a drug for MAUREEN TOOMEY commonly referred to as Ketek, 400 mg. for sinusitis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

5. That on or about August 24, 2005, MAUREEN TOOMEY filled a prescription for Ketek, 400 mgs. at WALGREENS, 2100 Green Bay Road, Evanston, Illinois, 60201.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

6. That on or about August 24, 2005, MAUREEN TOOMEY consumed the prescription drug commonly referred to as Ketek, 400 mg. until about mid-September, 2005.

**ANSWER:** Defendants are without knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 6 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

7. That on or about September 11, 2005, MAUREEN TOOMEY's urine became dark, and she began to have other symptoms including nausea.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

8. That on or about September 11, 2005, MAUREEN TOOMEY was treated by Emily Gottlieb, M.D., who performed a urinalysis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 8 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

9. That on or after September 11, 2005, results from the urinalysis of MAUREEN TOOMEY found bile in her urine and stones in her gallbladder.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 9 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

10. That on or about September 16, 2005, MAUREEN TOOMEY was admitted to Evanston Hospital.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 10 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

11. That on or about September 16, 2005, Evanston Hospital, through an agent or

employee, performed an ERCP which revealed MAUREEN TOOMEY had pancreatitis and an unknown caused hepatitis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 11 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

12. That on or about October 21, 2005, MAUREEN TOOMEY was re-admitted to Evanston Hospital.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 12 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

13. That on or about October 21, 2005, a CT scan of MAUREEN TOOMEY determined she had an extremely enlarged gallbladder from the hepatitis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 13 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

14. That on or about October 21, 2005 continuing through December 12, 2005, MAUREEN TOOMEY was treated with Augmentin.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 14 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

15. That on or about December 12, 2005, MAUREEN TOOMEY was admitted to Evanston Hospital for laparoscopic surgery.

**ANSWER:** Defendants are without knowledge or information sufficient to form a

belief as to the truth of the allegations contained in Paragraph 15 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

16. That in late February, 2006, MAUREEN TOOMEY started to experience arthralgia, and consulted with Emily Gottlieb, M.D., and a neurologist at Evanston Hospital, and it was determined she had carpal tunnel syndrome.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 16 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

17. That on or about May 9, 2006, MAUREEN TOOMEY was treated by Richard M. Green, M.D. of Northwestern Memorial Hospital, and he diagnosed MAUREEN TOOMEY with autoimmune Hepatitis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 17 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

18. That on or about May 12, 2006, MAUREEN TOOMEY checked into the Mayo Clinic of Rochester, Minnesota, where they prescribed her with 40 mg. of Prednisone.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 18 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

19. That in August, 2006, MAUREEN TOOMEY was treated by Cheryl Wilkes, M.D., who told her she could not return to work due to the stress.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 19 of Plaintiff's Complaint and,

therefore, can neither admit nor deny said allegations.

20. That in November 2006, MAUREEN TOOMEY was treated by Mark Moltch, M.D., and he told her all of her medical problems had returned.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

21. That on or about January 12, 2007, MAUREEN TOOMEY was treated by Christy Park, M.D., who diagnosed her with inflammatory poly arthritis, which was a complication of her autoimmune hepatitis.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 21 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

22. That on and prior to August 24, 2005, the drug manufacturer, SANOFI-AVENTIS, knew the drug Ketek caused adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and is only to be used in mild to moderate cases of community-acquired pneumonia.

**ANSWER:** API admits only that it had knowledge of certain adverse events associated with the use of Ketek®, which events were reported to the United States Food and Drug Administration ("FDA"). By way of further response, API states that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law. Sanofi-aventis U.S. Inc. denies that it manufactured Ketek® and denies all allegations contained in Paragraph 22 of Plaintiff's

Complaint directed to it. Except as stated herein, Paragraph 22 of Plaintiff's Complaint is denied.

23. That on and prior to August 24, 2005, the drug manufacturer, SANOFI-AVENTIS, was aware patients were prescribed and took Ketek were experiencing adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

**ANSWER:** API admits only that it had knowledge of certain adverse events associated with the use of Ketek®, which events were reported to the FDA. By way of further response, API states that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law. Sanofi-aventis U.S. Inc. denies that it manufactured Ketek® and denies all allegations contained in Paragraph 23 of Plaintiff's Complaint directed to it. Except as stated herein, Paragraph 23 of Plaintiff's Complaint is denied.

24. There prior to August 24, 2005, there was no warning in the Physician's Desk Reference on the package insert for the drug commonly referred to as Ketek regarding adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

**ANSWER:** Defendants deny that they failed to warn, label or disclose the risks associated with the use of Ketek®. Rather, Defendants state that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law. Defendants further state that Ketek®'s FDA-approved labeling and the Physicians' Desk Reference speak for themselves, and Defendants denies any



attempt by Plaintiff to characterize Ketek®'s FDA-approved labeling or the Physicians' Desk Reference inconsistent with their express terms. Except as stated herein, Paragraph 24 of Plaintiff's Complaint is denied.

25. That prior to August 24, 2005, there were no warnings to physicians, and consumers including the plaintiff from SANOFI-AVENTIS about Ketek causing adverse reactions including hepatitis, jaundice, chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

**ANSWER:** Defendants deny that they failed to warn, label or disclose the risks associated with the use of Ketek®, and deny that they had any obligation to warn the general consuming public, as alleged, including Plaintiff. Rather, Defendants state that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law. Except as stated herein, Paragraph 25 of Plaintiff's Complaint is denied.

26. That on or about August 24, 2005, the package insert regarding the drug Ketek and the drug Ketek received by the pharmacist at WALGREENS and the Plaintiff, was in the same condition as when it left the manufacturer's, WALGREENS, control.

**ANSWER:** Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 26 of Plaintiff's Complaint and, therefore, can neither admit nor deny said allegations.

27. That on or about August 24, 2005, the package insert regarding the drug Ketek and the drug Ketek given to MAUREEN TOOMEY by the pharmacist at WALGREENS did not include any warnings about Ketek causing adverse reactions including hepatitis, jaundice,

chronic pain, as well as carpal tunnel syndrome, and should not be used for sinusitis.

**ANSWER:** Defendants deny that they failed to warn, label or disclose the risks associated with the use of Ketek®. Rather, Defendants state that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law, and which speaks for itself. Defendants deny any attempt by Plaintiff to characterize Ketek®'s FDA-approved labeling inconsistent with its express terms. Except as stated herein, Paragraph 27 of Plaintiff's Complaint is denied.

28. That on and prior to August 24, 2005, the manufacturer and distributor of prescription drugs had a duty to warn consumers such as MAUREEN TOOMEY of the dangers and adverse reactions of those drugs as well as indications for use.

**ANSWER:** Paragraph 28 of Plaintiff's Complaint attempts to set forth legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that they had any obligation to warn the general consuming public, as alleged, including Plaintiff. By way of further response, Defendants state that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law. Except as stated herein, Paragraph 28 of Plaintiff's Complaint is denied.

29. That the drug Ketek was unreasonably dangerous in one or more of the following respects:

- a) Did not warn about the side effects of Ketek including jaundice and chronic pain; or
- b) Did not warn against the adverse reaction of hepatitis and carpal tunnel

syndrome; or

- c) Did not include that Ketek is only to be used in mild to moderately severe cases of community-acquired pneumonia; or
- d) Was otherwise unreasonably dangerous.

**ANSWER:** Defendants expressly deny that Ketek® was unreasonably dangerous at any time material to Plaintiff's Complaint when used in accordance with its FDA-approved labeling and for its intended purpose, deny that they failed to warn, label or disclose the risks associated with the use of Ketek®, deny that Ketek®'s FDA-approved indications were not adequately described in its FDA-approved labeling and, therefore, deny all allegations contained in Paragraph 29 of Plaintiff's Complaint, including all subparts. By way of further response, Defendants state that the potential adverse effects of Ketek® and its FDA-approved indications were adequately described in its FDA-approved labeling, which was at all times material to Plaintiff's Complaint adequate and comported with applicable standards of care and law, and which speaks for itself.

30. That as a proximate result of one or more of the foregoing unreasonably dangerous conditions MAUREEN TOOMEY was injured, has experienced pain and suffering; has been disabled and disfigured; has incurred expenses for medical, prescription, therapy, and other similar expenses; and has lost wages.

**ANSWER:** Paragraph 30 of Plaintiff's Complaint attempts to set forth legal conclusions to which no answer is required. To the extent an answer is required, Defendants expressly deny that Ketek® was unreasonably dangerous at any time material to Plaintiff's Complaint, deny any wrongful conduct pertaining to Plaintiff, deny that they caused or contributed to Plaintiff's alleged injuries or damages, if any, and, therefore, deny all allegations contained in Paragraph 30 of Plaintiff's Complaint.

WHEREFORE, Defendants deny that they caused or contributed to Plaintiff's alleged injuries, if any, deny that Plaintiff is entitled to any damages from Defendants and, therefore, deny all allegations contained in such Paragraph.

### **SEPARATE AND AFFIRMATIVE DEFENSES**

Discovery and investigation may reveal that any one or more of the following defenses are available to Defendants. Defendants therefore assert these defenses in order to preserve the right to assert them. By asserting the following affirmative defenses, Defendants do not allege or admit that they have the burden of proof and/or the burden of persuasion with respect to any of these matters:

#### **FIRST DEFENSE**

Plaintiff's claims are or may be barred by the applicable statute(s) of limitations and/or repose and must be dismissed.

#### **SECOND DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were or may have been due to the contributory and/or comparative negligence of Plaintiff, and/or those acting at her direction or control, in failing to exercise due and proper care under the existing circumstances and conditions, thereby barring recovery or reducing her damages by the doctrines of contributory or comparative negligence.

#### **THIRD DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, to the extent not caused by the negligence or fault of Plaintiff, may have been proximately caused by the negligence, fault, action or inactions of persons or entities other than Defendants, over whom Defendants had no control, and for such negligence, faults, actions, or inactions, Defendants are

not responsible.

#### **FOURTH DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation sold by Defendant API or other sellers, thereby barring Plaintiff from recovery.

#### **FIFTH DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were not proximately caused by the use of Ketek® or by any acts or omissions on the part of Defendants.

#### **SIXTH DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were caused directly, solely and proximately by sensitivities, medical conditions and idiosyncrasies peculiar to Plaintiff not found in the general public, and were unknown, unknowable or not reasonably foreseeable to Defendants.

#### **SEVENTH DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were the result of pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, or were otherwise due to causes unrelated Ketek®.

#### **EIGHTH DEFENSE**

Plaintiff's claims are preempted by federal or state law, and any regulations or rules promulgated thereunder, including but not limited to the Federal Food, Drug & Cosmetic Act (hereinafter, "FDCA"), 21 U.S.C. § 301 *et. seq.*, and the United States Constitution, Article IV,

clause 2.

#### **NINTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, under the applicable state law because Ketek® was subject to and received pre-market approval by the FDCA under 52 Stat. 1040, 21 U.S.C. § 301 *et. seq.*

#### **TENTH DEFENSE**

The injuries and damages allegedly suffered by Plaintiff in this action, if any, were the result of nature or other intervening, superseding causes other than Defendants and, therefore, any alleged action or conduct on the part of Defendants was not the proximate and/or competent producing cause of the alleged injuries.

#### **ELEVENTH DEFENSE**

If Ketek® was involved in the injuries and damages allegedly suffered by Plaintiff in this action, which is denied, the use of Ketek® was improper and/or not in accordance with prescribed, correct procedures. Accordingly, Ketek® was unforeseeably altered, handled, abused, misused and/or applied for purposes other than those which were indicated, intended or foreseen by Defendants, thereby barring Plaintiff's claims.

#### **TWELFTH DEFENSE**

Plaintiff's claims are barred because Ketek® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time, and the risks complained of by Plaintiff were not discoverable using prevailing research and scientific techniques under the then-existing state-of-the art and knowledge and were not discoverable using procedures required by federal or state regulatory authorities charged with supervision of Ketek® as of the time Defendant API sold or otherwise parted with possession and control of

Ketek®.

### **THIRTEENTH DEFENSE**

Plaintiff's claims are barred because Ketek® was manufactured, labeled, packaged, advertised and promoted in accordance with all applicable statutes, codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

### **FOURTEENTH DEFENSE**

Plaintiff failed to exercise reasonable care and diligence to mitigate her injuries and/or damages allegedly suffered, if any.

### **FIFTEENTH DEFENSE**

Plaintiff's claims based on any alleged duty to warn are barred because Defendant API satisfied its duties under the "learned intermediary" doctrine.

### **SIXTEENTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Ketek® is not defective or unreasonably dangerous because it is a prescription pharmaceutical bearing adequate warnings, and is subject to the comment "j" exception to strict tort liability as set forth in § 402A of the Restatement (Second) of Torts (1965); or because it is a prescription pharmaceutical that is unavoidably unsafe pursuant to comment "k" of § 402A of the Restatement (Second) of Torts (1965); or because Defendant API provided adequate and complete warnings to Plaintiff's prescribing physicians and, therefore, the product was not defective or unreasonably dangerous pursuant to § 6 of the Restatement (Third) of Torts: Product Liability; or because Ketek® "provides net benefits for a class of patients" within the meaning of comment "f" to § 6 of the Restatement (Third) of Torts: Product Liability; or because of the application of § 4 *et seq.*, of

the Restatement (Third) of Torts: Product Liability.

**SEVENTEENTH DEFENSE**

Plaintiff's claims are barred because the utility of Ketek® outweighed its risks.

**EIGHTEENTH DEFENSE**

Plaintiff's claims must be dismissed because Plaintiff would have taken Ketek® even if the product labeling contained the information that Plaintiff contends should have been provided.

**NINETEENTH DEFENSE**

Plaintiff's claims are barred because Plaintiff did not justifiably rely on activities attributed by Plaintiff to Defendants in the Complaint, and any injuries or damages complained of in the Complaint were not caused by Defendants' alleged actions.

**TWENTIETH DEFENSE**

Plaintiff's claims are barred and/or this Court should defer in this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction and exhaustion of remedies, in that FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint, and is charged under the law with regulating prescription drugs, including Ketek®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the Plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

**TWENTY-FIRST DEFENSE**

Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by FDA under the FDCA.



**TWENTY-SECOND DEFENSE**

To the extent Plaintiff's claims are based on alleged misrepresentations made to FDA, such claims are barred pursuant to Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

**TWENTY-THIRD DEFENSE**

Plaintiff's claims for strict liability are barred as to Defendants inasmuch as they are not manufacturers of Ketek® within the meaning of the Illinois Product Liability Act, 735 ILCS 5/2-621, and other applicable Illinois law.

**TWENTY-FOURTH DEFENSE**

The liability of Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the Plaintiff and each and every other person whose fault could have contributed to Plaintiff's alleged injuries and damages, if any.

**TWENTY-FIFTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Ketek® were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

**TWENTY-SIXTH DEFENSE**

To the extent that application of conflicts of laws rules to the claims asserted in the Complaint yields a legal conclusion that the claims asserted are not governed by the laws relied upon in the Complaint, Defendants plead and preserve all defenses which flow from the application of those conflicts rules and which flow from the application of the correct rule of law.

**TWENTY-SEVENTH DEFENSE**

Plaintiff's Complaint fails to state a claim against Defendants upon which relief may be granted and, therefore, must be dismissed.

**TWENTY-EIGHTH DEFENSE**

Defendants did not breach any duty of care to Plaintiff.

**TWENTY-NINTH DEFENSE**

Plaintiff's claims are barred, in whole or in part, because Ketek was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

**THIRTIETH DEFENSE**

Plaintiff has failed to join all necessary and indispensable parties.

**THIRTY-FIRST DEFENSE**

Defendants reserve the right to assert any additional separate and affirmative defenses at a later date.

**JURY DEMAND**

Defendants demand a **TRIAL BY JURY** as to Plaintiff's claims.

**WHEREFORE**, Defendants having fully responded to Plaintiff's Complaint, demand:

- a. **TRIAL BY JURY;**
- b. That judgment is entered in Defendants' favor;
- c. That any and all claims for compensatory damages, medical expenses, physical, mental, emotional and/or conscious pain and suffering or other personal injuries or damages or expenses be denied;
- d. That any and all claims for special damages for medical expenses, lost wages, lost

earning capacity, physical pain and mental anguish, or disfigurement and physical impairment be denied;

e. That all costs be taxed to Plaintiff; and

f. That this Court enter an award or such other and further relief to Defendants as it deems just and proper.

Respectfully submitted this 2nd day of January 2008.

DONOHUE, BROWN, MATHEWSON &  
SMYTH LLC

/s/ Bryan J. Kirsch  
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(404) 885-3900 (facsimile)

**CERTIFICATE OF SERVICE**

I hereby certify that on January 2, 2008, I caused to be electronically filed: Defendants Answer, Jury Demand and Separate and Affirmative Defenses with the Clerk of the Court using the CM/ECF System that will send notification of such filing(s) to the following:

Joseph A. Power, Jr.	<a href="mailto:joepower@prslaw.com">joepower@prslaw.com</a>
Donald J. Brown, Jr.	<a href="mailto:donald.brown@dbmslaw.com">donald.brown@dbmslaw.com</a>
Byran J. Kirsch	<a href="mailto:byran.kirsch@dbmslaw.com">byran.kirsch@dbmslaw.com</a>

And I hereby certify that on January 2, 2008, I caused to be mailed by United States Postal Service, a copy of the above-named documents to the following non-registered participants:

Michael C. Holy  
Johnson & Bell, ltd.  
33 W. Monroe Street  
Suite 2700  
Chicago, IL 60603-5404

DONOHUE, BROWN, MATHEWSON &  
SMYTH LLC

/s/ Bryan J. Kirsch  
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